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S. 1415 — The National Tobacco Policy and Youth Smoking Reduction Act

Highlights of the McCain Modification (“Commerce-2”)

Update . . . Update . . . Update

NOTEWORTHY

- Yesterday at a White House ceremony and in a letter to the Senate leadership, President Clinton announced his support for this bill, as modified, noting his work in helping to “strengthen” it.
- On Monday, May 18, a modification of S. 1415 (as reported by the Commerce Committee on May 1) was presented to the desk, and became the underlying bill. A procedure was utilized whereby the Commerce modification (what we call “Commerce-2”) displaced the bill reported last week by the Finance Committee [Calendar No. 370]. What is now before the Senate as the fully amendable bill is “Commerce-2”, a bill which is a complete substitute for the original Commerce-reported bill, and which contains part (but not all) of the Finance-reported version. Some of the rejected provisions from Finance, likely will be offered as floor amendments. Further, a Lugar farm bill (a modified version of S. 1313, the Tobacco Transition Act) was also added as a further modification to “Commerce-2.”
- Commerce-2 contains many substantive changes from its predecessor. This Legislative Notice Update is not a comprehensive summary of Commerce-2. Rather, it is a quick summary of the key *differences* between Commerce-2 and the original reported bill. Many provisions remain largely or virtually unchanged, and for those, we refer you to Legislative Notice No. 67 of May 14, 1998, which is a detailed look at the bill as reported.

BILL PROVISIONS

Sec. 1: Short Title and Table of Contents

Sec. 2: Findings [Commerce-2 retains all the originally reported bill's findings, and adds two more, one dealing with environmental smoke (12), and another (34) addressing tobacco products in movies and the mass media.]

Sec. 3: Purpose [Commerce-2 retains the 19 purposes of the reported bill, making these changes: (1) "clarify" rather than "confirm" FDA authority; (5) penalties will be imposed on manufacturers "if tobacco use by young people does not substantially decline"; (9) now says "disclose research" rather than "disclose all research"; (11) deletes reference to funding source for standards on smoking in public places, and adds language restricting the state from electing not to accept federal standard: it can opt out only "if that State's standard is as protective, or more protective, of the public health".]

Sec. 4: Scope and Effect [Commerce-2 deletes two provisions regarding punitive damages (see reported bill, p. 255).]

Sec. 5: Commerce-2 re-titles this section as "Relationship to Other, Related Federal, State, Local and Tribal Laws" [Retains the age restrictions, additional measures, and authority of states to spend funds, and adds a new provision that any local law that is "not less stringent" will not be superseded by this act.]

Sec. 6: Definitions [Commerce-2 deletes from this section that definition for "consent decree," "master settlement agreement," "participating tobacco product manufacturer," "non-participating tobacco product manufacturer," and "protocol." [Note: for a discussion of these entities, see the bill's new Title XIV.] Commerce-2 also expands "tobacco product manufacturer" to include importers [Commerce-2, p. 23] and slightly modifies definitions for Indian lands and "smokeless tobacco".]

Sec. 7: Notification if Youthful Cigarette Smoking Restrictions Increase Youthful Pipe and Cigar Smoking [Commerce-2 strengthens the mandate in this section (compare reported bill, p. 263, to Commerce-2, p. 24.)]

Commerce-2 deletes the old "Sec. 8: Liability Provisions Disappear if Tobacco Product Manufacturers Challenge Advertising Limits" [Bill, pp. 263-264]

Sec. 8: FTC Jurisdiction Not Affected [new section number, identical language].

Sec. 9: Congressional Review Provisions [new section number, identical language].

Title I — Regulation of the Tobacco Industry

- **Sec. 101, Amendment of Federal Food, Drug, and Cosmetic Act (FDCA) of 1938.**
The most significant change in this section is that Commerce-2 would now prohibit

FDA from banning tobacco sales for single class of retailers. As reported, the bill gave FDA authority to ban tobacco sales from entire categories of retail stores (e.g., convenience stores, drug stores, etc.).

- Commerce-2 modifies Sec. 906 of the Federal Food, Drug, and Cosmetic Act [that new section was created in the reported bill] to prohibit FDA from banning “the sale of any tobacco product in face-to-face transactions by a specific category of retail outlets.”
- In addition, Commerce-2 modifies Sec. 102, “No-Tobacco-Sale Orders,” to allow the FDA to impose “no tobacco sales orders” to permanently prohibit an individual retail outlet from selling tobacco products (Sec. 102, p. 92) for “repeated violations” (to be defined by final regulation), such as failure to check ID allowing individuals under age 18 to purchase tobacco.
- Commerce-2 also strikes Sec. 915 requiring the FDA to establish a nine-member “Tobacco Products Scientific Advisory Committee.” Commerce-2 replaces references to the nine-member committee with general language referring to “an advisory committee” that will give recommendations to the FDA with respect to proposed tobacco regulations.
- Commerce-2 also adds a new Sec. 103 regarding FDA rules in effect and limitation on FDA advisory opinions. Language deeming to be in effect the FDA’s August 28, 1996, final regulations has been moved from Section 901(c) of the reported version to Section 103 (p. 99) of Commerce-2. This new language makes it clear that the 1996 regulations are deemed to be lawful under the proposed new chapter IX (i.e., provisions of title I of this bill) of the FDCA and not under chapter V of the FDCA (which governs regulation of medical devices) as originally provided in the 1996 regulations.
 - In addition, Section 103 of the substitute adds language stating that FDA may not use the tobacco regulations as the basis for regulating other medical devices.
 - Specifically, the substitute provides that FDA documents published as part of the 1995 proposed rule and the 1996 final rule on tobacco “shall not constitute advisory opinions” nor serve as binding precedents except as they apply to tobacco products [Sec. 103, pp. 99-100].
- The reported bill had contained a “Subtitle B — Tobacco Advertising,” but advertising provisions are moved to Title XIV in Commerce-2.

Title II — Reductions in Underage Tobacco Use

Subtitle A — Underage Use

- Commerce-2 adds a Findings provision [Sec. 201, p. 100] and a Purpose [Sec. 202].
- Sec. 203 [formerly Sec. 201] remains Goals for Reducing Underage Tobacco Use.

- **Sec. 204 [formerly Sec. 202], Look-Back Assessment:** The reduction targets set forward in the bill remain the same; however, the process for determining whether the targets have been met is quite different.
 - The Secretary must conduct a survey to determine annually (1) the percentage of all young individuals who used tobacco within the past 30 days; and (2) the percentage of young individuals who identify each brand of each type of tobacco product they used within the past 30 days [Sec. 204(a)].
 - **Commerce-2 no longer requires the use of the University of Michigan study, but lays out a specific methodology that must be followed.** The survey must permit the calculation of the actual percentage reductions in underage use based on the survey's estimates of the percentage of kids reporting use of a type of tobacco product. The estimates are deemed conclusively to be correct and accurate.
- Sec. 204(e) now provides that the industry-wide non-attainment penalties remain the same, **unless non-attainment is more than 21.6 percent, in which case the penalty is capped at \$4 billion.**
- The provision [formerly Sec. 203] that required the **removal of the civil liability cap** if industry and individual tobacco manufacturers failed to meet the non-attainment percentages by more than 20 percent is now included in Title 14 regarding the protocol [Sec. 1404(d)].
- Sec. 204(f) adds a **new company-specific penalty** to Commerce-2. Each tobacco manufacturer must reduce the percentage of kids who use that manufacturer's specific brand or brands by the reduction targets in Sec. 203. **Failure to do so results in a penalty of \$1,000 per underage user in excess of the yearly reduction target.**

Subtitle B — State Retail Licensing and Enforcement Incentives

- **Sec. 231, State Retail Licensing and Enforcement Block Grants [formerly Sec. 213]:** This section on State enforcement incentives is **significantly modified** and renamed Sec. 231. This section now provides \$200 million per year in retail licensing and enforcement block grants to States.
- **A state is eligible to receive a block grant** (based on population) if the State (1) has a law requiring a license to distribute tobacco, (2) has a law making it illegal to sell or distribute tobacco products to kids under age 18, and (3) enters into an agreement with the Secretary that the State promises to do the following:
 - assume responsibility for the implementation and enforcement of a tobacco retailer licensing program;
 - prohibit retailers from selling or distributing tobacco products to kids under 18 in accordance with new FDA regulations;
 - provide any information required by the Secretary on retailers who sell tobacco products to any Federal agencies designated by the Secretary;
 - prove to the Secretary's satisfaction that a State has:

- ▶ a law mandating a state license to sell tobacco;
 - ▶ a law mandating a retail establishment purchase tobacco only from a federally licensed manufacturer;
 - ▶ a program to provide notification to retail establishments;
 - ▶ criminal penalties for the sale of tobacco without a license;
 - ▶ civil penalties for the sale of tobacco products in violation of State law; and
 - ▶ other programs, including fines, suspension of driver's licenses and community service requirements for underage kids who possess, purchase, or attempt to purchase tobacco products [Commerce -2, Sec. 231(b)].
- **States receiving a block grant must enforce compliance with their retail licensing program** in such a manner that the sale of tobacco products to kids under 18 is reduced. The Secretary may withhold grant funds for failure to comply.
 - As was the case in the bill as reported, a state must —to enforce compliance— conduct monthly, random, unannounced inspections of retailers. However, the bill no longer specifies the number of inspections, but rather outlines standards to ensure that inspections are conducted in a way to ensure a “scientifically sound estimate”. *[Note that on May 14, RPC issued a paper, entitled, “S. 1415 Creates a New State Retail Inspection Regime,” addressing the provisions in the bill as reported.]*
 - A state is in noncompliance if it fails to demonstrate a compliance rate of (1) at least the annual targets in the Synar Amendment prior to its repeal through the 3rd fiscal year; (2) at least 80 percent in the 4th fiscal year; (3) 85 percent in the 5th and 6th years; and (4) 90 percent in the 7th year. These targets are higher than proposed in the bill as reported.
 - Like its predecessor, Commerce-2 mandates that the Secretary promulgate regulations establishing a federal tobacco retail licensing program if a State does not participate in the block grant.
 - **Sec. 232, Block Grants for Compliance Bonuses:** This section authorizes \$100 million per year to be appropriated from the National Tobacco Trust Fund to provide grants to States that demonstrate to the satisfaction of the Secretary *that fewer than 5 percent of all kids* under 18 are able to successfully purchase tobacco products.
 - Commerce-2 also differs from its predecessor in that it authorizes a specific expenditure and does not require that States deliver half of the funds to retailers.

Subtitle C — Tobacco Use Prevention and Cessation Initiatives *[formerly National Smoking Cessation Program]*

- **Sec. 221, Tobacco Use Prevention and Cessation Initiatives:** Commerce-2 significantly modified this section. Rather than a whole new bureaucracy, this bill creates a new Title 19 of the Public Health Service Act (PHSA) to provide smoking cessation block grants.
- Commerce-2 specifies the amounts to be authorized under the program:

- The bill authorizes 25-35 percent of amounts in the public health account for cessation and other treatments [see Sec. 451(b)(2)(A)].
- The bill authorizes 50-65 percent of amounts in the public health account for education, prevention, and counter-advertising [see Sec. 451(b)(2)(C)].
- **PHSA Sec. 1981A** provides funds to the States for prevention and cessation needs. These monies will be allocated based on a formula developed by the Secretary, and distributed through the Director of the Centers for Disease Control and Prevention ("Director").
- **PSHA Sec. 1981B** allows the Secretary, acting through the Director, to provide a State technical assistance and training with respect to the planning, development, operation and evaluation of any program or service. However, no more than 10 percent of the funds available for cessation may be used by the Secretary for these activities.
- **PSHA Sec. 1981C(a)** lists the permissible uses of the cessation block grants including:
 - evidence-based cessation activities designed to assist individuals, especially young people and minorities to quit;
 - training in cessation intervention methods for health plans and health professionals;
 - demonstration programs to encourage health insurers and health plans to provide coverage for evidence-based tobacco-use cessation interventions and therapies;
 - culturally and linguistically appropriate programs targeted toward minority and low-income individuals, individuals residing in medically under-served areas, uninsured individuals, and pregnant women;
 - programs to encourage employer-based wellness programs to provide evidence-based tobacco-use cessation intervention and therapies; and
 - programs that target populations whose smoking rate is disproportionately high.
- **PHSA Sec. 1981C(b)** lists the permissible uses of the education and prevention block grant, including:
 - State and community initiatives;
 - community-based prevention programs, similar to programs now funded by NIH;
 - programs focused on populations that are most at risk or have been targeted by tobacco advertising or marketing;
 - school programs to prevent and reduce tobacco use and addiction, including school programs in areas with high smoking rates;
 - culturally and linguistically appropriate initiatives targeted toward minority and low-income individuals, individuals residing in medically under-served areas, uninsured individuals, and pregnant women;
 - development and implementation of tobacco-related public health and health promotion campaigns and public policy initiatives;
 - assistance to local governmental entities to conduct appropriate anti-tobacco activities;
 - strategies to ensure smoking prevention activities include minority, low-income and other under-served populations; and
 - programs that target populations with a disproportionately high smoking rate.

- **PSHA Sec. 1981C(c)** allows the tobacco-use cessation and community-based prevention activities to be conducted in conjunction with other federally funded programs, including WIC, Children's Health Insurance Program, school lunch, and seven other listed federal programs.
- **PSHA Sec. 1981C(d)** prohibits monies received by a State to:
 - make cash payments (except with appropriate documentation);
 - fund educational, recreational, or health activities not based on scientific evidence that the activity will prevent smoking;
 - purchase or improve land; purchase, construct, or permanently improve any building;
 - satisfy any requirement for the expenditure of nonfederal funds as a condition of the receipt of federal funds; or
 - provide financial assistance to any entity other than a public or nonprofit private entity.
- **PSHA Sec. 1981D** requires a State to submit an application to the Secretary in order to receive a grant. The application must include a state plan. That plan must (1) provide for tobacco-use cessation intervention and treatment consistent with certain guidelines; (2) provide training in tobacco-use cessation intervention methods for health plans and health professionals; (3) ensure access to tobacco-use cessation programs for rural and under-served populations; (4) recognize that some individuals may require more than one attempt for successful cessation.
- **PSHA Sec. 1981E** provides the guidelines for a state advisory committee; establishment of such a committee is encouraged for purposes of having its state plan certified.
- **Commerce-2** also significantly modifies the provisions of the National Tobacco-Free Public education campaign [formerly Sec. 222]. This provision is now included in the new Title 19 of the Public Health Service Act.
- **PHSA Sec. 1982** requires the Secretary to conduct a national counter-advertising campaign to reduce teen smoking and discourage smoking by individuals. The National Tobacco Education Advisory Board is established to evaluate and provide long-range planning for the development and effective dissemination of public information.
 - This new section lists the requirements of the Board including appointment of its 12 members; terms of the appointments; powers and duties.
 - Those eligible to receive grant monies are: a public entity or State health department; or private or nonprofit private entity that is not affiliated with a tobacco company and has a demonstrated record of working to reduce tobacco use or has expertise in conducting a multi-media campaign.
 - Twenty-five percent of the funds received under this program must be allocated to states for state and local media-based and non-media based education, prevention and cessation campaigns. No more than 20 percent of the monies can be used for the development of new messages; and no more than 1/2 of 1 percent can be used for administrative costs.

- **No monies will be provided for counter-advertising under this section if the annual amount appropriated to CDC is less than the amount appropriated the prior year.**
- Some of the provisions formerly in Subtitle A of Title XI (Miscellaneous) of the bill as reported are now moved to Title II in Commerce-2 and included in the newly created Title XIV of Public Health Service Act.
 - ***PHSA Sec. 1991* prohibits the expenditures of funds by NIH, CDC, and Agency for Health Care Policy and Research in any fiscal year in which the annual amount appropriated for these agencies is less than the amount appropriated in the prior fiscal year.**
 - ***PHSA Sec. 1991A* authorizes the Secretary to enter into a \$750,000 contract with the Institute of Medicine to conduct a study on the “framework for a research agenda and research priorities.”**
 - ***PHSA Sec. 1991B* requires the Secretary (rather than a Task Force) to foster coordination among public health agencies, academic bodies, and community groups with respect to tobacco-related research.**
 - ***PHSA Sec. 1991C* gives the Director of CDC authority to carry out tobacco-related surveillance and epidemiologic studies and develop tobacco control and prevention strategies. The funds are to come from amounts in the Health and Health-Related Research Account, but not less than 12 percent and not more than 18 percent of the funds can be used for this purpose.**
 - ***PHSA Sec. 1991D* authorizes the appropriations of \$25 billion over 10 years to the National Institutes of Health for “research related to the prevention and treatment of tobacco addiction, and the prevention and treatment of diseases associated with tobacco use.” The funds are to come from the Health and Health-Related Research Account, but not less than 75 percent and not more than 80 percent of the funds can be used for this purpose.**
 - ***PHSA Sec. 1991E* authorizes the Administrator of the Agency for Health Care Policy and Research to carry out health services research related to effective interventions for the prevention and cessation of tobacco use.**

Title III — Product Warnings and Smoke Constituent Disclosure

Subtitle A — Product Warnings, Labeling and Packaging

- Sec. 301 remains Cigarette Label and Advertising Warnings and Sec. 302 remains Authority to Revise Cigarette Warning Label Statements.
- Sec. 303 remains Smokeless Tobacco Labels and Advertising Warnings but adds a subsection (c) making it unlawful to advertise smokeless tobacco on television and radio [p. 175].
- Sec. 304 remains Authority to Revise Smokeless Tobacco Product Warning Label Statements.

- Sec. 305 remains Tar, Nicotine, and Other Smoke Constituent Disclosure to the Public.

Subtitle B — Testing and Reporting of Tobacco Product Smoke Constituents

- Sec. 311 remains Regulation Requirement.

Title IV — National Tobacco Trust Fund

[formerly "National Tobacco Settlement Trust Fund"]

This Title has changed substantially. RPC will be issuing a separate paper on the budgetary and spending aspects of title IV of Commerce-2.

Subtitle A — General Payment Provisions

- Sec. 401 remains Establishment of Trust Fund. *Commerce-1 contained a Sec. 402, "State Litigation Settlement Account." Commerce-2 creates a single trust fund with separate accounts for State, Public Health, Health Research, and Farmer Assistance.*
- Sec. 402 [formerly Sec. 403] is now Payments by Industry.
- Sec. 403 [formerly Sec. 404] is now Adjustments.
- Sec. 404 [formerly Sec. 405] is now Payments to be Passed Through to Consumers.
- Sec. 405 [formerly Sec. 406] is now Tax Treatment of Payments.
- Sec. 406 [formerly Sec. 407] is now Enforcement for Nonpayment.

Subtitle B — General Spending Provisions

- The reported version of the bill contained a section authorizing additional funds for child care and early childhood development [reported bill, Sec. 412]. **Funding for child care has been moved to Title XI of Commerce-2.**
- Commerce-2 has a new section Sec. 451, Allocation Accounts [pp. 192-199]. Under Commerce-2, revenues within the Trust Fund's four accounts will be allocated as follows:
 - **State Litigation Settlement Account:** 40 percent of the Trust Fund's net receipts will be distributed among the states for this account. The distribution formula will be worked out by the Treasury Secretary, the National Governors Association, the National Association of Attorneys General, and the National Conference of State Legislators. States may use these funds "as the State determines appropriate" [p. 193].
 - **Public Health Account:** 22 percent of the Trust Fund's net receipts will be distributed to this account to be used for cessation treatment (to receive between 25 and 35 percent of the allocation); Indian Health Service activities (to receive between 3 and 7 percent); education and prevention activities (to receive

between 50 and 65 percent); and **enforcement activities** (to receive between 17.5 percent and 22.5 percent).

- ▶ **Enforcement funds are further divided among FDA** (guaranteed over half of enforcement funds beginning in second year); **state retail licensing activities**; and **anti-smuggling activities** [pp. 194-196].
- **Health Research Account: 22 percent** of the Trust Fund's net receipts will be allocated to this account, to be divided as follows:
 - ▶ **National Institutes of Health (NIH)** to receive between 75 and 80 percent of the allocation;
 - ▶ **Centers for Disease Control (CDC)** to receive between 12 and 18 percent;
 - ▶ **National Science Foundation** to receive 1 percent; and
 - ▶ **Cancer Clinical Trials** to receive \$750 million in first 3 years.
- **Farmers Assistance Account: 16 percent** will be allocated to this account for each of the first 10 years, 4 percent for each year thereafter until the account has received a total of \$28.5 billion.
- A new **Sec. 452, Grants to States** provides additional grants to states out of the \$10 billion up-front payment to be made by the five tobacco companies [Sec. 402(a)] as a precondition of entering the protocol [pp. 200-206].
 - 50 percent of the funds may be spent by states on any activities they choose.
 - At least 50 percent of these funds must be spent on various child health and welfare programs [pp. 200-206] as well as activities within the Safe and Drug-Free Schools Program and teacher training activities under the Eisenhower Professional Development Program.
- **New also is Sec. 453**, describing anti-tobacco activities to be funded within the Indian Health Service [pp. 206-207].
- **Sec. 454, Research at the National Science Foundation** is a new section [p. 207].
- **Sec. 455, Medicare Cancer Patient Demonstration Project; Evaluation and Report to Congress** is also new [pp. 207-210].

Title V — Standards to Reduce Involuntary Exposure to Tobacco Smoke

- Commerce-2 significantly modifies the state opt-out provision in **Sec. 502, Smoke-Free Environment Policy**. States and local governments may opt out by promulgating their own laws provided those laws are "...as or more *protective of the public's health* as this title, based on the *best available science*." (Emphasis added.) States and local

governments may opt to enforce this title themselves subject to certification by the Assistant Secretary.

- Commerce-2 expands the provisions in Sec. 502 from protecting the public from exposure to environmental tobacco smoke to protecting the public from the health effects of environmental tobacco smoke.
 - The Assistant Secretary, in promulgating the regulations to carry out the purposes of this title, now **must consult with the Administrator of the Environmental Protection Agency**. These two changes mean that the resulting regulatory regime will be driven by the EPA, **not the Assistant Secretary**.
 - Finally, the **opt-out provision could allow states or local governments to go well beyond the federal regulations**, as long as they go further to "protect public health." Theoretically, states or local governments could shorten or eliminate the 60-day notice provision for citizen actions and certain categories of "public facilities" now exempt could be subjected to state or local standards.
- Sec. 504 remains Preemption, Sec. 505 remains Regulations, and Sec. 506 remains Effective Date.

Title VI — Application to Indian Tribes

- Sec. 601 retains the short title, "Reduction in Tobacco Use and Regulation of Tobacco Products in Indian Country Act of 1998."
- Sec. 602 remains findings and purposes.
- Sec. 603 remains the application of this title to Indian Lands and to Native Americans.
- *In the reported version of the bill, Sec. 604 required tribes to collect state excise and sales taxes on tobacco and tobacco products purchased on Indian lands by non-Indians. This section is not contained in Commerce-2's Title VI, but we are informed that this was a drafting error. It will require unanimous consent to add this provision on the floor.*

Title VII — Tobacco Claims

[formerly titled, "Civil Liability of Tobacco Product Manufacturers"]

Title VII must be read together with Title XIV. Many of the rules that were contained in former Title VII are now split between Commerce-2's Title VII and XIV. New Title XIV applies only to participating tobacco manufacturers whereas new Title VII applies to all civil tobacco litigation.

- Sec. 701 remains Definitions, but what has been defined has changed. It contains numerous definitions that are applicable only to Title VII, including an extensive and particularized definition of what constitutes a "Castano Civil Action" [see Title XIV, pp. 426-427].

- Sec. 702 is now Application [formerly "Application; Preemption"]: Sec. 702(b) ensures that the requirement for the presumption preempts any state law to the contrary.
- **Sec. 703, Rules Governing Tobacco Claims** [*new section name*: This section is the gist of the title; it establishes that for all civil actions brought in any state, tribal, or federal court there will be a **"general causation presumption" that (1) nicotine is addictive and that (2) "diseases identified as being caused by use of tobacco products" in three named publications of the Public Health Service (issued in 1989 and 1986 [two]) are indeed caused, in whole or in part, by the use of tobacco products. All juries hearing tobacco claims are to be instructed with the "general causation presumption."**
- Deleted were Secs. 704-708, titled respectively, *"Governmental Claims and Castano Civil Actions," "Concurrent Jurisdiction; Federal Cause of Action; Actions, Damages; Liability," "Payment of Tobacco Claim Settlements and Judgments," "Attorney's Fees and Expenses," "Non-Participating Tobacco Product Manufacturers," [but see new Title XIV] and "Conforming Amendments."*

Title VIII — Tobacco Industry Accountability Requirements and Employee Protection from Reprisals [*modified title name*]

- Sec. 801 is now titled "Accountability Requirements and Oversight of the Tobacco Industry." Commerce-2 does not establish a new "Tobacco Agreement Accountability Panel" [TAAP, created in the reported bill] but simply adds the intent of the TAAP to the current responsibilities of its proposed members. It maintains the intent of the panel to report to Congress annually on tobacco manufacturing efforts to reduce youth smoking.
- Sec. 802 remains Tobacco Product Manufacturer Employee Protection.
- The reported bill allowed the TAAP the power to declare a **"public health emergency"** if its members unanimously determined that a manufacturer's actions present a "clear and present danger" to the attainment of underage smoking target levels, and if the FDA Commissioner determines the TAPP's report is supported by "clear and convincing evidence." The Commissioner could then bring a court action [see Sec. 203] seeking to **immediately suspend the manufacturer's annual cap on civil liability payments.** A similar provision is now found in Title XIV, Sec. 1410.
- The reported bill also included the requirement that if a manufacturer fails to meet its youth reduction targets by more than 20 percentage points, the Secretary must either (a) bring an action **suspending the civil liability cap** [Sec. 203], or (b) issue a finding that the manufacturer made "reasonable efforts" to reach attainment.

Title IX — Public Disclosure of Tobacco Industry Documents

- Sec. 901 remains Findings; and Sec. 902 remains Applicability.
- Sec. 903 is now Document Disclosure [*formerly National Tobacco Document Depository*]; [*Note that the depository provisions have been relocated to the new Title*

XIV. Under this title, the industry must voluntarily create the depository in exchange for benefits so provided.] Within 60 days of enactment, all tobacco product manufacturers must submit all required documents (see original legislative notice for description of documents) to the Food and Drug Administration. This amounts to a far shorter time period in which tobacco companies must submit documents. Under the bill as reported, companies had 180 days to create the depository and then 30 days to submit documents. Under Commerce-2, companies have only 60 days to submit documents — 150 less days.

- A new Sec. 904 is called Document Review. The reported bill created a National Tobacco Documents Review Board composed of five members appointed by the President with consent of the Senate, while Commerce-2 allows all claims of attorney-client privilege, trade secret protection, or other claims of privilege to be heard by a three-judge panel of the United States District Court for the District of Columbia.
- Sec. 905 is Resolution of Disputed Privilege and Trade Secret Claims [the former Sec. 904 was titled "Privilege and Trade Secret Claims"].
- Sec. 906 is Appeal of Panel Decision [the former Sec. 908 was titled "Appeal of Board Decision"]. Sec. 907 is Miscellaneous [formerly Sec. 909]. Sec. 908 is Penalties [formerly Sec. 910]. Sec. 908 allows the District Court panel to assess penalties of up to \$50,000 per violation for failing to produce documents — a 10,000 percent increase over Commerce-1. In addition, Commerce-2 increases the maximum penalty for repeated violations to \$5 million, from \$10,000 — a 50,000-percent increase. It also allows the District Court panel to assess penalties for good faith violations in asserting an attorney-client or trademark privilege of up to \$50,000 per violation — a 500-percent increase in penalties over the reported bill's provisions.
- Sec. 909 is Definitions [formerly Sec. 911].

Title X — Long-Term Economic Assistance for Farmers

This Title is substantially the same as Title X in the reported bill, "Long-term Economic Assistance for Farmers Act" (the "LEAF Act"), except that it no longer establishes the Tobacco Community Revitalization Trust Fund [see Title IV].

- Sec. 1011 authorizes appropriations: "There are appropriated and transferred to the Secretary for each fiscal year such amounts from the National Tobacco Trust Funds established by section 401 . . . as may be necessary to carry out the provisions of this title." Accordingly, this would be mandatory spending.
- See also Title XV for the Lugar proposal.

Title XI — Miscellaneous

Title XI has been changed substantially. Commerce-1 contained eight subtitles; Commerce-2 has four (and only three of those were in Commerce-1). Commerce-2 retains the subtitles on International Provisions, Anti-Smuggling, and Vending Machines. (We do not mean to imply

that the contents of the titles are identical (which they are not), only that the subject matter of the titles' headlines are comparable.) The Finance Committee added a new section in Subtitle C (Other Provisions) on health coverage for mastectomies and related procedures. The following Subtitles and sections have either been moved or deleted:

- *Former subtitle A, sections 1101-1105 relating to prohibitions on advertising and sale of tobacco in foreign countries have been deleted;*
- *Former subtitle A, section 1106 regarding NIH, CDC, Institute of Medicine provisions can now be found in Title II, Subtitle C;*
- *Former subtitle B, section 1121 regarding the licensing fee has been deleted (although the Treasury Secretary is given authority to establish an appropriate licensing fee to cover the cost of administering and enforcing Subtitle B) while the licensing requirement can be found in Subtitle B, section 1133;*
- *Former subtitle E regarding a limited anti-trust exemption has been deleted;*
- *Former subtitle F regarding special provisions concerning programs for women and minorities can now be found in Title II, Subtitle C; and*
- *Former subtitle G regarding a Sense of the Senate on spending provisions has been deleted.*

Subtitle A — International Provisions [formerly Subtitle C]

The provisions in this subtitle have changed substantially. The most significant changes are the deletion of former section 1131 establishing the International Tobacco Control Trust Fund, and section 1132 creating the American Center on Global Health and Tobacco (ACT). This title was an area addressed by the Senate Finance Committee.

- **Sec. 1101, Policy:** This section provides that the United States should pursue a bilateral and multilateral agreement that includes measures to restrict tobacco advertising, to require warning labels, and to limit access to kids.
- **Sec. 1102, Tobacco Control Negotiations:** Gives the Secretary of HHS and the United States Trade Representative (USTR) authority to negotiate the bilateral and multilateral agreements.
- **Sec. 1103, Report to Congress:** Requires a report within 150 days after enactment of this bill a report identifying the international arenas where negotiations might occur.
- **Sec. 1104, Funding:** Authorizes the funds necessary to carry out the provisions of this subtitle.
- **Sec. 1105, Prohibition of Funds to Facilitate the Exportation or Promotion of Tobacco:** This section bars any appropriations or use of funds by any officer, employee, department or agency to (1) promote the sale or export of tobacco products, or (2) seek the reduction or removal by any foreign country of restrictions on the marketing of tobacco or tobacco products, unless such restrictions are not applied equally to all tobacco. *[This section incorporates the Finance Committee amendment in substance, but modifies the language slightly and adds additional statutory requirements]*
- **Sec. 1106, Health Labeling of Tobacco Products for Export:** Requires exports to either be labeled in the same manner as tobacco distributed domestically, or comply with specific health hazard warning labeling requirements of the exporting country.

- **Sec. 1107, International Tobacco Control Awareness:** This section authorizes the appropriation of \$3.5 billion over 10 years for the Secretary to establish an international tobacco control awareness effort. The Secretary is authorized to make any necessary grants and may transfer to any agency of the United States any part of any funds appropriated for the purpose of this section.

Subtitle B—Anti-smuggling Provisions [*smuggling provisions were previously contained in Subtitle D*]

- **Sec. 1131, Definitions:** Includes additional definitions for exporter, importer, intentionally, manufacturer and wholesaler.
- **Sec. 1132, Tobacco Product Labeling Requirements** [formerly Sec. 1142]: This section applies the labeling and “unique serial number” requirement to importers, as well as manufacturers. Commerce-2 also simply requires that the exported product “be marked for export”, instead of noting the country of final destination.
- **Commerce-2 deletes former section 1143** which required all exporters of tobacco to post a bond with the Secretary of the Treasury.
- **Sec. 1133, Tobacco Product Licenses** [formerly Subtitle B] and **Sec. 1134, Prohibitions** [formerly Sec. 1145]: These two sections require tobacco manufacturers to obtain a license in order to import, manufacture, wholesale or export tobacco products.
 - Commerce-2 makes the licensing program effective one year after enactment of the bill. The former bill had made the program effective 180 days after enactment. Commerce-2 also modified former section 1145 to require a license for the export of tobacco products.
 - This section also makes it unlawful for the (1) unlicensed receipt or delivery of any tobacco product; (2) receipt of reimported tobacco products; (3) delivery by a licensed exporter to any person other than a licensed manufacturer or foreign purchaser; (4) shipment of tobacco packages marked “FOR EXPORT FROM THE UNITED STATES” other than for direct return or re-exportation; and (5) intentional false entry in, willful failure to make appropriate entry in or willful failure to properly maintain any record or report as required by this chapter.
- **Sec. 1135, Labeling of Products Sold by Native Americans** [formerly Sec. 1146, Pricing and Labeling on Military Installations and by Native Americans]: Commerce-2 deleted the provision mandating the price of tobacco products on military installations.
- **Sec. 1136, Limitation of Activities Involving Tobacco Products in Foreign Trade Zones** [formerly Sec. 1147, Prohibition against Duty-Free Shops]: Commerce-2 deletes the prohibition against selling tobacco products in Duty-Free shops, but maintains the section making it illegal to forward through or manufacture any tobacco product in any foreign trade zone.
- **Sec. 1137, Jurisdiction; Penalties; and Compromise of Liability** [formerly Sec. 1148]: Commerce-2 increases penalties for violations of this subtitle by allowing not only

finances as provided in section 3571 of Title 18 United States Code, but also **imprisonment for not more than five years** or both. In addition, the Secretary of the Treasury may, in lieu of criminal prosecution, impose civil penalties not to exceed \$10,000 for each offense.

- Commerce-2 also permits the Secretary to **seize property** which constitutes or is derived from proceeds traceable to violations of this subtitle.
- **Sec. 1138, Amendments to the Contraband Cigarette Trafficking Act [formerly Sec. 1149]:** Commerce-2 adds a requirement that anyone advertising, shipping, selling or distributing tobacco products in interstate commerce must file with the tobacco tax administrator of the State into which tobacco shipments or advertisements are made.
 - In addition, the person must file with the state tobacco tax administrator a memorandum with the recipient's name and the brand and quantity of the product received, or an invoice copy of each and every tobacco product sent into the State.
- **Sec. 1139, Funding:** This section gives the Secretary of the Treasury authority to establish **licensing fees** in such amounts as are necessary to recover the costs of administering and enforcing provisions of this chapter.
- **Sec. 1140, Rules and Regulations:** Permits the Secretary to prescribe all necessary rules and regulations.

Subtitle C—Other Provisions

- **Sec. 1161, Improving Child Care and Early Childhood Development:** This section is new in Commerce-2 [formerly in the non-binding Sense of the Senate in Subtitle G]. It authorizes the appropriation of "**such sums as necessary**" from the National Tobacco Trust Fund for child care programs within the Child Care and Development Block Grant. The committee report recommended \$4 billion per year be diverted to child care activities from the Trust Fund.
 - These funds are to be in addition to any funds otherwise available and can be used for a broad range of child care activities including (1) improving the **affordability of child care**; (2) enhancing the **quality of child care**; (3) expanding the **availability of school-age care**; and (4) **assisting young children** by providing grants for parent education, supportive services, strengthening the quality of child care, improving health services, and improving services for children with disabilities.
- **Sec. 1162, Ban of Sale on Tobacco Products Through the Use of Vending Machines:** [*This is the same language as that formerly contained in Subtitle H, sec. 1191*].
- **Sec. 1163, Amendments to the Employee Retirement Income Security Act of 1974:** This section amends ERISA by adding Senator D'Amato's language prohibiting so-called **drive-by mastectomies** [*note that the language is slightly modified from that agreed to by the Senate Finance Committee last week*].

Title XII — Asbestos-Related Tobacco Claims

[formerly "Tobacco Asbestos Trust Fund"]

- Sec. 1201 is **National Tobacco Trust Funds Available Under Future Legislation**. Unlike the reported bill, Title XII of Commerce-2 does not establish a Tobacco Asbestos Trust Fund. Instead, the new, short Title XII allows money to be transferred from the National Tobacco Trust Fund for asbestos claims *if* Congress "enacts qualifying legislation" which changes the allocation of funds "set aside for public health expenditures under title IV."

Title XIII — Veterans' Benefits

- Sec. 1301 remains **Recovery by Secretary of Veterans Affairs**, but was modified somewhat. Commerce-2 broadens language in this title specifying that the Secretary of the Department of Veterans Affairs can also sue tobacco manufacturers to recover the costs for **providing medical care services** to veterans rather than limiting recovery to compensation costs.
- The language also allows funds recovered by the Secretary for those medical services provided to veterans to be credited to the **Veterans Affairs Tobacco Recovery Fund**. The monies recovered will be available to the Secretary for veterans' programs [rather than available only for veterans' benefits programs].
- Commerce-2 limits lawsuits that can be brought by the Veterans Secretary to **tobacco product manufacturers** [deleting language in the reported bill allowing suits to be brought also against distributors or retailers], but allows the Secretary to establish regulations and determine and establish the present value of **medical care services** to be provided to the veteran.

Title XIV — Exchange of Benefits for Agreement to Take

Additional Measures to Reduce Youth Smoking *[new title, begins on p. 408]*

- **Sections 1401-1403, General Provisions of the Protocol:** These three sections set forth the requirements that tobacco manufacturers must meet under the protocol. To become a "participating tobacco product manufacturer" for purposes of the act, a manufacturer must execute a protocol with the Secretary of Health and Human Services and must make the payments required under Title IV of the bill.
 - Specifically, tobacco companies are required to make an up-front payment of \$10 billion in order to participate in the protocol. This amount is in addition to the annual payments tobacco companies are required to pay. [Sec. 1402]
 - A manufacturer may not become (or will cease to be) a participant if convicted of, among other offenses: distributing a misbranded product, violating IRS reporting requirements, committing mail fraud or wire fraud, or making false statement to federal officials. [Sec. 1402]

- **Sec. 1403, General Provisions for Protocol:** The protocol must contain the following provisions:
 - Manufacturers may not engage in any conduct that is prohibited by the act, prohibited by the 1996 FDA tobacco regulations, or prohibited by any other statute.
 - Manufacturers may contract with only those distributors and retailers who are in compliance with all federal, state, and local tobacco laws and who agree to comply with the advertising restrictions contained in the bill.
 - The advertising and marketing provisions of the 1996 FDA tobacco regulations as well as the labeling and advertising restrictions in section 1404 must be incorporated as independent terms of the protocol.
 - Manufacturers must make all payments required under title IV and all other titles of the bill, including industry-wide and manufacturer-specific look-back payments under title II.
 - Manufacturers executing the protocol will have 180 days to establish a National Tobacco Document Depository in the Washington, D.C. area. Construction and operating costs of the Document Depository will be allocated among participating manufacturers.
 - **Sec. 1404, Labeling and Advertising Restrictions [formerly Title I, Sec. 122]:** These provisions are substantially the same as those in the Committee reported bill, with the exception of two provisions, which have been deleted, and one new provision that was added:
 - Commerce-2 deletes the requirement that tobacco products bearing the words "light" or "low tar" must also carry a disclaimer stating that the product is "no less hazardous than any other tobacco product"; and
 - This legislation also deletes the requirement that all cigarette and smokeless tobacco labels carry the words "A Nicotine Delivery Device."
 - Commerce-2 adds language prohibiting tobacco advertising on mass transit vehicles.
 - **Sec. 1405, Point-of-Sale Requirements [formerly Sec. 123, Title I]**
- Section 1406 begins the civil liability sections. Interspersed among the civil liability sections are other provisions from the Committee reported bill. In general, the provisions of Commerce-2 are substantially similar to the provisions of the Committee reported bill.*
- **Sec. 1406, Application of Title [similar to former section 702]**
 - **Sec. 1407, Governmental Claims [similar to former section 704(a) & (b)]**
 - **Sec. 1408, Addiction and Dependency Claims; Castano Civil Actions [similar to former section 704(c)]**
 - **Sec. 1409, Substantial Non-attainment of Required Reductions [similar to former section 203]**

- **Sec. 1410, Public Health Emergency** [similar to former section 801(d)]
- **Sec. 1411, Tobacco Claims Brought Against Participating Tobacco Product Manufacturers:** similar to former section 705, although Commerce-2 deleted provisions protecting parent companies from liability.
- **Sec. 1412, Payment of Tobacco Claim Settlements and Judgments:** similar to former section 706, but the annual liability cap has been raised from \$6.5 billion to \$8 billion and the Attorney General must establish "a mechanism for implementing" the aggregate cap in a "fair and equitable" manner.
- **Sec. 1413, Attorneys' Fees and Expenses** [similar to former section 707]
- **Sec. 1414, Effect of Court Decisions:** Provides that most sections of the bill are severable; however, provisions of Title XIV are not severable, and "a final decision substantially limiting or impairing the essential elements" of Title XIV (especially section 1404 and 1405) may bring down the entire title.
- **Sec. 1415, Criminal Laws Not Affected**
- **Sec. 1416, Congress Reserves the Right to Enact Laws in the Future**
- **Sec. 1417, Definitions**

Title XV — Tobacco Transition

This new title provides Senator Lugar's "Tobacco Transition Act" which aids tobacco farmers. [For details on this title, and for a comparison with the "Leaf Act" provisions (contained in Title X of the reported bill), see RPC's paper, entitled "A Look at the Lugar Tobacco Buyout Proposal Contained in the Tobacco Bill, 5/19/89.]

ADMINISTRATION POSITION

While the Administration did not issue an official policy statement, yesterday President Clinton did send a letter to Majority Leader Lott offering his support for the bill as modified (i.e., Commerce-2, but without Title XV), calling it "a good strong bill," and urged the Senate to pass it "without delay." At a White House ceremony, he noted the White House's work "with senators in both parties to strengthen this bill."

COST

The Congressional Budget Office (CBO) has not yet scored this bill and says it will be unable to do so until after Memorial Day.

POSSIBLE AMENDMENTS

In addition to those already offered, here are other likely amendments. This is not comprehensive.

Domenici/Gramm. Anti-smoking, anti-drug substitute that addresses youth smoking and drug issues without settling state lawsuits.

Hatch/Feinstein. substitute based on the original June 20, 1997 tobacco settlement.

Conrad. Substitute.

Coverdell/Craig. Anti-drug amendment.

Enzi. Regarding tobacco revenue receipts.

Enzi. Regarding Medicare and state block grants to Medicaid/teen smoking prevention programs.

Durbin/DeWine. Regarding look-back penalties.

Sessions. Regarding the National Tobacco Compensation Fund.

Roth. Tax credits for health insurance for uninsured and the self-employed.

Nickles. Regarding taxes.

Bond. Increase self-employed health insurance deduction.

Chafee. International flight smoking ban.

Burns. Re: vending machine reimbursement.

Lugar. Motion to strike Title X (LEAF Act).

Ford. Motion to strike Title XV (Tobacco Transition Act).

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